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TITLE: Remote Interactive Monitoring of Patients on
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DHP RFS
Final Report

Remote Interactive Monitoring of Patients on Anticoagulant Therapy to Improve Outcome and Avoid Complications
Proposal Number: 1999000211

Jennifer Lynn Calagan Ph.D., M.D.

Abstract

Problems

This project suffered a multitude of problems/challenges and as a result is approximately two years behind in operation. The key initial requirement was to modify the existing DCI-approved protocol to meet the provisions of the Telemedicine study. After review of the amendments, DCI felt that the changes were of a magnitude which necessitated an entirely new protocol submission. The new protocol and consent from went through a complete approval process including committee appearances, requested revisions and sample size recalculation. Some of the other requirements of the project could be pursued at the same time as the approval process was underway: most could not (e.g., staff could not be hired prior to approval being imminent, space could not be acquired until it was ready to be used. Acquiring staff was difficult as well, and chart reviews and eligibility determinations awaited staff.

As of May 2001, the first patient was enrolled into the pilot portion of the project. The pilot portion of the project will enroll and monitor 8 patients separately from the main population of 400. The official start of the one- year project starts once the 400 patient population is enrolled into the project. Below is an outline of problems listed by category:

INFRASTRUCTURE NEEDS: - Acquiring Office Space for Staff and Patient Care/Counseling - (Still trying to get space for patient care/counseling) - Acquiring Communications (Phone / LAN) Support - (3 month delay in getting support: installations of hardware required) - Acquiring Staff Personnel - (8 months to get qualified nurse practitioner) - Available Patient Parking (not modifiable by us, but impacts patient recruitment) - (patient may take up to an hour to find parking before getting into the building)

ADMINISTRATIVE NEEDS: - No Existing Operational Patient Coumadin® Record

System - (Had to review over 800 paper records to identify who was active and set up basic database to identify active and inactive clinic patients) - Making 400 copies of Project Patient Medical Record - (Once patients are enrolled into program, a new separate medical record has to be set up that includes the old information and the project consent form and new project specific forms)

SCIENTIFIC/CLINICAL NEEDS: - Design of Required Project Forms - (20 specific forms where developed with informational content) - Conduct Manual Review of Medical Records - Creation of Master Patient Record for each of Four Groups - (There are four groups of patients of 100 patients each and each group has its own specific set of forms that have been worked and reworked and through DCI for approval) - Eligibility determinations - Randomization procedures and randomization - Development of custom HealthBuddy® questions and dialogues. These then need to be programmed into the system for deployment.

TECHNICAL NEEDS: - Creation of a Patient Tracking System/Database - (The project with its 20 unique forms for data collection requires an extensive custom relational database that requires a database programmer to set up and maintain. We have identified the individual table and field characteristics, and are pending a programmer to implement the project. The database is expected to be available by August 15, 2001. The information for the database will be collected and maintained in the patient paper medical record until the database is ready.)

PROTOCOL AND CONSENT FORM APPROVALS THROUGH LOCAL DCI - Human Use Committee - Clinical Investigation Committee - Institutional Review Board

LOGISTICS/TRAINING: - Acquiring Required Equipment and Supplies in a Timely Manner - (The military system for purchasing is extremely slow and has delayed the project where critical support items have been required such as computers.) - Patient Scheduling for Initial Half-Day Coumadin® Clinic Briefing - (It is very difficult to get patients in for the scheduled formal briefing/training sessions on Coumadin®. With class size limited to five to seven patients each, the process is very slow.) - Patient Scheduling for Enrollment into Coumadin® Project - (All patients enrolled fill out enrollment forms, are given Consent forms to review and then questions answered. Patient must be trained in standard Coumadin® Therapy. Once trained they then are scheduled to train in the ITC ProTime® blood testing device and the HHN HealthBuddy®. If patients do not pass the training phases, they are not assigned into a standard study group. This process is very time consuming.

TRAINING: - Initial Staff Training on: - ITC ProTime® Device - (Extensive and physically painful training was required to master the device prior to training patients on it.) - HHN HealthBuddy® Device - (Training was easy but did require an additional amount of time) - HHN Server Application - (This training provided staff members the functionality to use the home monitoring systems collected data for following up on patient reported results and the tools available to manipulate the data for study purposes.) - Patient Training on: - Coumadin® Therapy - (This training provided the patients the required medical background for them to understand the therapy they are receiving, that each person's therapy is unique, and that severe complications can ensue if Coumadin® therapy is not managed properly. - ITC ProTime® Device - (The ITC ProTime® device is a difficult and painful device to use as the patient has to puncture a finger, get their blood into a cuvette and insert the cuvette into the device all with 2 minutes. Patients going through the training session would sometimes try 4 or 5 times to

master the process so they could participate in the study.) - HHN HealthBuddy® - (Patient training on the HHN HealthBuddy® included the set-up and operation of the device. Patients have to disconnect their home telephone and place this HealthBuddy® inline with their phones).

Deliverables

This project has no specific deliverables other that the finding from the study which should be available in approximately a year and half. Since patients are followed for one year after enrollment, and enrollment is proving extremely time consuming, end date is one year from last enrollment. This will necessitate extending the nurse practitioner beyond one calendar year from hire.

Expenditures

Element of Resource (EOR)	3Q FY 00 Apr 1 - May 31	4Q FY 00 Jun 1 - Sep 30	1Q FY 01 Oct 1 - Dec 31	2Q FY 01 Jan 1 - Mar 31	TOTALS
Travel 2100	0.00	0.00	3,500.00	0.00	3,500.00
Shipping 2200	0.00	0.00	0.00	0.00	0.00
Rent & Communications 2200	0.00	0.00	0.00	0.00	0.00
Contract for Services 2500	0.00	0.00	181,773.00	0.00	181,773.00
Supplies 2600	0.00	0.00	4,440.00	0.00	4,440.00
Equipment 3100	0.00	0.00	12,128.00	0.00	12,128.00
GRAND TOTALS	0.00	0.00	201,841.00	0.00	201,841.00

Financials

Personnel: Principle Investigator (20%): Military LTC Project Manager (30% FTE): $40,000 Nurse Practitioner (100% FTE): $89,306 Research Consultant (10% FTE): $18,867 Data Management Technician (20% FTE): $10,000 Telemedicine Logistics (Percentage): $23,600 ----------- $181,773

Clinic Equipment: Storage Cabinet (2): $423 File Cabinet: $211 Shredder: $150 PC (3): $9,470 Printer: $1,344 Answering Machines (3): $95 Refrigerator: $435 -------- $12,128

Travel: $3,500

Clinic Office Supplies: $1,834

Expendable Medical Supplies: $2,606 ---------- $201,841

Project disbursements are self-explanatory. There is approximately $35,000 held in a holding account to cover an extension of the Nurse Practitioner and to cover the cost of any lost or damaged equipment that has been provided to the government at no cost.

Virtual Costs or equipment provided at no charge to the government for this project include:

Home Health Hero Network System Site Fee: $50,000 Patient Activation/Health Buddy® (200 devices @ $100 ea): $20,000 Monthly Usage Fee (200 devices @$15 per month*12 mon): $36,000 ---------- $106,000

ITC ProTime® Device Purchase Fee (200 devices @$1,500 each): $300,000

--------- Total $406,000

Final Results

ACQUISITIONS

- Personnel - Project Manager ? - Nurse Practitioner ? - Research Associate ? - Data Management Technician

- Equipment & Supplies - Office Equipment ? - Office Supplies ? - Medical Equipment - HealthBuddies® [25%] - ProTime® Units [4%] - Medical Supplies [4%]

ADMINISTRATIVE SUPPORT

- Develop Project Work Breakdown Structure ? - Develop New Human Use Research Protocol and Obtain Approvals ? - Develop New Patient Consent Form and Obtain Approvals ? - Develop and Process No- Cost Agreements ? - Develop Specialized Project Forms ? - Develop Master Patient Records ? - Prepare Copies of Patient Record (420 copies) [25% Complete] - Develop Patient Tracking System/Database [20% Complete] - Enter Patient Data into Tracking System/Database [Pending] - Develop Equipment Issue Process ? - Develop Patient Selection Process ? - Develop Randomization Process ? - Develop Patient Training Program ? - Develop Clinical Business Process

CLINICAL STAFF TRAINING

- Clinic Process ? - ITC ProTime® Device ? - HHN HealthBuddy® Device ? - HHN Software Application ?

PATIENT CARE/SUPPORT

- Qualification ? - Selection ? - Randomization ? - Training (ITC and HHN Devices) [ongoing] - Enrollment [ongoing]

? = activity complete

Projected Costs

Start Up Cost for a Medical Center (supporting 200 Patients) in a non-study mode:

Initial Year---Following Years Home Health Hero Network System One-time Site Fee:
$50,000--------------None Patient Activation/Health Buddy (200 devices @ $100 ea):
$20,000----------$20,000 Monthly Usage Fee (200 devices @$15 per month*12 mo):
$36,000----------$36,000 ITC ProTime® Device Purchase Fee (200 devices @$1,500 each):
$300,000-------------None

Expendable Medical Supplies: $2,000-----------$2,000

Nurse Practitioner (1 Year FTE): $105,000---Existing Staff

Equipment Costs: $10,000-------------None Totals $523,000----------$58,000

Comments

Due to the complexity of this project with enrolling and monitoring 400+ patients for one year after the last patient is enrolled, this project will require additional funds to maintain the contracted nurse practitioner. The nurse practitioner follows self-monitored patients and provides patient care depending on which of the four groups the patient falls into. Additional funds will also be required to mine the data and complete the study evaluation.

TATRC Scientific Review

TATRC Acquisition Review

Supporting Graphs/Charts

No Attachments